

REMARKS**A. Background**

Claims 13-25 were pending in the application at the time of the Office Action. Claims 13-18 and 20-24 were rejected as being anticipated over cited prior art and claims 19 and 25 were rejected as being obvious over cited prior art. By this response Applicant has amended claims 13, 20, and 23 and added new claims 26 and 27. As such, claims 13-27 are presented for the Examiner's consideration in light of the following remarks.

B. Proposed Claim Amendments

Applicant has amended claims 13, 20, and 23 to more clearly convey that the gas is recirculated back through the enclosure after the gas has already been through the enclosure a first time. Applicant has also added claims 26 and 27 to claim heating of the gas in the preparation region. All of these amendments are supported in the application as originally filed. In view of this, applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

C. Rejection on the Merits

Initially, applicant would like to thank the examiner for the courtesy of the telephone interview conducted on September 14, 2005. The purpose of the interview was to clarify the Examiner's position as to why the independent claims were rejected over the U.S. patent Number 4,952,370 to Cummings et al. ("the '370 patent") and what would be required to overcome the rejections. Based on our discussion, the Examiner agreed, pending a more thorough examination, that the '370 patent does not disclose a gas that is recirculated back through the enclosure after the

gas has already been through the enclosure a first time. It was initially discussed amending the independent claims to recite "continuously" circulating to clarify the distinction. On further consideration, however, it appears that "continuously recirculating ... over a period of time" will more clearly support the distinction. As such, the independent claims have been amended accordingly. The Examiner agreed that if the Applicant's claims were amended to clarify the distinction, this would likely differentiate over the '370 patent. No formal agreement was reached with the Examiner.

The Office Action rejected claims 13-18 and 20-24 under 35 U.S.C. §102(b) as being anticipated by the '370 patent. Applicant respectfully traverses this rejection.

The '370 patent is directed towards a method of sterilizing a sealed enclosure containing surfaces at two disparate temperatures while maintaining the disparate temperatures of the surfaces. The method consists of injecting vapor phase hydrogen peroxide and water into the enclosure through inlet ports (22 and 24) to form a condensate on the surface with the lower temperature. A vacuum pump (40) is then used to evaporate the water within the enclosure and remove it. Abstract and col. 3, lines 51-53. As will be discussed below in greater detail, the removed water vapor is processed to remove any hydrogen peroxide and is then dispensed to the atmosphere. The vacuum pump (40) is used to maintain a pressure within the enclosure "above the vapor pressure of hydrogen peroxide and below the vapor pressure of water at the relevant temperature." Col. 3, lines 61-65. By maintaining the pressure in the enclosure between the two vapor pressures, the water evaporates out of the condensate while the hydrogen peroxide does not, resulting in a higher concentration of hydrogen peroxide in the condensate that remains on the cold surface. Col. 3, lines 65-68. Another purpose of the vacuum is to "remove... much of the water vapor to avoid a build up of water vapor in the chamber." Col. 4, lines 17-19.

Additional vapor phase hydrogen peroxide is periodically injected into the enclosure through inlet ports (22 and 24) to replace hydrogen peroxide condensate that degrades into its components (water and oxygen) over time and the vacuum pump continues to remove the water vapor as it evaporates. Col. 4, lines 127-19. This process of periodically injecting hydrogen peroxide while withdrawing water vapor under a vacuum continues until the surfaces within the enclosure are sterile. The hydrogen peroxide condensate is then removed from the system by using the vacuum pump to further reduce the pressure in the enclosure so as to cause the hydrogen peroxide condensate to evaporate. Col. 6, line 63 – col. 7, line 2. Once the hydrogen peroxide is removed from the sealed enclosure, the hydrogen peroxide is processed and then discharged to the environment.

Applicant submits that the hydrogen peroxide and the water vapor removed from the enclosure are not recirculated back through the enclosure. The '370 patent uses a vaporizer converter (42) for both vaporizing liquid hydrogen peroxide before injecting it into the enclosure, and for processing water vapor and hydrogen peroxide vapor that is removed from the enclosure before discharging it to the environment. These functions are separate and distinct, even though vaporizer converter (42) is shown in Figure 2 as being a single unit. Specifically, vaporizer converter (42) "includes two chambers, one for vaporizing liquid hydrogen peroxide solutions and one for promoting the degradation of hydrogen peroxide vapor exhausted from a chamber into water and oxygen for discharge." Col 5, lines 41-46. The '370 patent does not disclose or suggest any mixing of gases between the two chambers of vaporizer converter (42), and because the vaporizing and degradation functions are separate and distinct, there is no reason to direct any gas from either chamber to the other. The '370 patent simply does not disclose or suggest recirculating any gas or hydrogen peroxide vapor back through the enclosure after the gas or hydrogen peroxide vapor has been removed from the enclosure.

Furthermore, applicant submits that there is no motivation for recirculating any gas that it is evacuated from the enclosure of the '370 patent back into the enclosure. As discussed above, during the sterilization process, the vacuum pump (40) is used to regulate the pressure within the enclosure so that water vapor can be removed under the vacuum while the hydrogen peroxide remains in the enclosure. The '370 patent teaches that the water vapor is removed "to avoid a build up of water vapor in the chamber." Col. 4, lines 18-19. Accordingly, because the gas that is drawn out of the enclosure during the sterilization process is primarily water vapor, there is not motivation to recirculate this gas back into the enclosure since it would defeat the objective of trying to remove the water vapor. Although the hydrogen peroxide is removed from the enclosure after the sterilization process, there is no motivation to pass this hydrogen peroxide back into the enclosure because the enclosure is already sterile.

In view of the forgoing, applicant submits that the '370 does not disclose or suggest recirculating a gas through the enclosure and there is no motivation to modify the reference to recirculate a gas. As such, applicant submits that the '370 patent does not disclose or suggest a method of sterilizing an enclosure which includes a step of "continuously recirculating a gas through the enclosure and through a preparation region for a period of time," as recited in claim 13, or an apparatus which includes "means (8) for continuously recirculating a gas through a preparation region (3) and through the enclosure (1) for a period of time," as recited in claim 20.

Claims 14-18 depend from claim 1 while claims 21-24 depend from claim 20 and thus incorporate the limitations thereof. As such, applicant submits that claims 14-18 and 21-24 are distinguished over the cited art for at least the same reasons as discussed above with regard to claims 13 and 20. Accordingly, Applicant respectfully requests that the anticipation rejection with respect to claims 14-18 and 21-24 also be withdrawn.

The Office Action rejected claims 19 and 25 under 35 U.S.C. § 103(a) as being unpatentable over the '370 patent in view of U.S. Patent No. 4,909,999 to Cummings et al. ("the '999 patent"). The '999 patent was merely cited for disclosing the use of catalytic decomposition means when removing the decontaminant gas from the enclosure.

Claims 19 and 25 depend from claims 13 and 20, respectively, and thus incorporate the limitations thereof. Even if the catalytic decomposition means of the '999 patent were combined with the '370 patent, the combination would still not cure the deficiencies of the '370 patent, described above. As such, Applicant submits that even assuming *arguendo* that the '370 patent and the '999 patent were combined in the manner asserted by the Office Action, claims 19 and 25 are still distinguished over the combination for at least the same reasons as discussed above with regard to claims 13 and 20. Thus, Applicant respectfully requests that the obviousness rejection with respect to claims 19 and 25 be withdrawn.

Applicant submits that many if not all of the dependent claims may also be independently distinguishable over the '370 patent. For example, new claims 26 and 27 recite "heating the gas" (in claim 26), and "means for heating the gas" (in claim 27) "in said preparation region prior to circulation through the enclosure." The '370 patent does not disclose any heating of or means for heating water vapor or hydrogen peroxide vapor before injection into the enclosure, and actually teaches against this. Specifically, one of the stated purposes of the '370 patent is to maintain the cool temperature of the enclosure during sterilization. To achieve this objective, the vacuum is used so that the hydrogen peroxide and water can be vaporized without applying heat. Thus, the '370 patent does not disclose heating of the gas or means for heat the gas since such methods and structures are in direct contrast to the intended function and operation of the system of the '370 patent. As such, applicant also submits that claims 26 and 27 are allowable over the cited prior art.

No other objections or rejections are set forth in the Office Action.

D. Conclusion

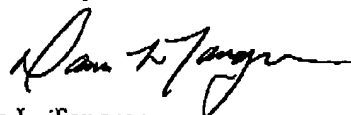
Applicant notes that this response does not discuss every reason why the claims of the present application are distinguished over the cited prior art. Most notably, applicant submits that many if not all of the dependent claims are independently distinguishable over the cited art. Applicant has merely submitted those arguments which it considers sufficient to clearly distinguish the claims over the cited art.

In view of the foregoing, applicant respectfully requests the Examiner's reconsideration and allowance of claims 13-27 as amended and presented herein.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Dated this 19th day of October 2005.

Respectfully submitted,



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